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510K SUMMARY
AS REQUIRED BY 21 CFR 807.92

K980590

1. Submitter:

Varian Oncology Systems
3045 Hanover Street
Palo Alto, CA 94304

Contact: Linda S. Nash, Manager
Regulatory Compliance & Radiation Safety
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Prepared: February 12, 1998
Revised: July 23, 1998

2. Device Name: VariSource Henschke Type GYN Applicator for Varian VariSource™ Remote High Dose Rate Afterloader.

3. Predicate Device: Mick Radio-Nuclear Instruments, Inc., Henschke Afterloading Applicator, K871217.

4. Description: Applicators for the Varian VariSource Remote High Dose Rate Afterloader are a part of a remote controlled radionuclide applicator system, including an electromechanical device to enable an operator to apply, by remote control, a radionuclide source of high activity at various internal or surface body locations for radiation brachytherapy. The shape and materials of the applicator determine where it will be utilized for treatment.

5. Intended Use: The Varian VariSource Remote High Dose Rate Afterloader [system, including applicators and accessories] is a device intended to be used by properly trained and licensed medical personnel to provide radiation brachytherapy The VariSource Henschke Type GYN Applicator which is the subject of this 510(k) is a component of the VariSource system.

6.Technological Characteristics: See attached comparison sheet.

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Comparison to Predicate Device

#	Feature	MRNI Henschke Afterloading Applicator K871217	VariSource Henschke Type GYN Applicator K980590
1	Afterloading Method	Manual	Remote HDR
2	Coupling Catheter Fittings	No	Yes
3	Tandem		
	Diameter and material	6 mm, Stainless steel	6/3 mm, Stainless Steel
	Configuration	Straight, Medium Curved, & Maximum Curved	Straight, Medium Curved, & Maximum Curved
	Cervical Stop	Yes	Yes
4	Colpostat		
	Diameter and material	6 mm, Stainless steel	6/3 mm, Stainless Steel
	Configuration	1 left, 1 right	1 left, 1 right
5	Spacing/locking Bracket	Aluminum	Aluminum
6	Hemispherical Ovoids		
	Diameter and material	2 cm, Delrin	2cm, Polysulfone
7	Ovoid Caps		
	Diameter and material	2.5 cm & 3.0 cm, Delrin	2.5 cm & 3.0 cm, Polysulfone
8	Ovoid Inserts	Tungsten shields and Delrin fillers	Tungsten shields and Polysulfone fillers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

Linda Nash
Regulatory Compliance
and Radiation Safety Manager
Varian Associates, Inc.
3045 Hanover Street
Palo Alto, CA 94304

Re: K980590
VariSource Henschke Type GYN Applicator
for VariSource HDR Afterloader
Dated: July 24, 1998
Received: July 28, 1998
Regulatory class: II
21 CFR 892.5700/Procode: 90 JAQ

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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STATEMENT of INDICATIONS for USE*

I state in my capacity as Manager, Regulatory Compliance and Safety, of Varian Oncology Systems that the Product which is the subject of this premarket notification, is intended to be used for the following:

> The Varian VariSource™ Remote High Dose Rate Afterloader [system, including applicators and accessories] is a device intended to be used by properly trained and licensed medical personnel to provide radiation brachytherapy. The VariSource Henschke Type GYN applicator which is the subject of this 510(k) is a component of the VariSource system.

Charles H. Will, Manager
Regulatory Compliance & Safety

February 12, 1998
Date

*Suggested language and format to meet the requirements of section 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and 21 CFR sections 801.4 and 809.92(a)(5).

K980590
510(k) Number

Division Sign-off
Office of Device Evaluation

Prescription Use ✓ (Per 21 CFR 801.109)

Over-the-Counter Use _____